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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,495	12/30/2003	Charles R. Roe	BHCS:1007RCE	8734

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,495	ROE, CHARLES R.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/19/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19-47 and 49-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,19-47 and 49-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 17, 19-47 and 49-57 are pending. Claims 19, 21, 23-25, 30, 34, 38, 42, 47, 49, 53 and 56 are currently amended.

The response filed **11/19/07** presents remarks and arguments to the office action mailed **8/17/07**. Applicants' request for reconsideration of the rejection of claims in the last office action is acknowledged.

Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "..provide relief to said patient.." It is however unclear the degree of relief provided. The term "provide relief" in claim 42 is a relative term which renders the claim indefinite. The term "provide relief" is not defined by the claim, the

specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 47-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "...obtains nutrition from odd carbon fatty acid metabolism". Is the odd carbon fatty acid the n-heptanoic acid or other odd carbon fatty acid? Clarification is required.

Claims 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "between about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "between" (Intermediate to, as in quantity, amount, or degree) or "about"(broadening limitation, both higher and lower) controls the metes and bounds of the phrase "between about".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17, 21-25, 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over buchmann et al., US 6,225,347as evidence by Iwama et al., Internal Medicine, vol. 36(9) 1997, 613-617.

The reference teaches administering acid radicals of hepatonic acid for the treatment of cardiac dysrhythmia such as myocardial a cardiac disorder. See col. 3, lines 10-22 and also col. 11, lines 5-11 as required by instant claims 17. The reference also teaches the heptanoic acid radical to exist as straight or branched and unsaturated as required by instant claim 21, see col. 4, lines 41.

The reference also teaches the various routes of administration, orall-known as enteral administration and parenterally. See col. 11, lines 27-28.

The reference however fails to teach explicitly the cardiac disorder as either cardiac muscle weakness or myopathy nor explicitely identifying heptanoic acid as n-heptanoic acid.

It would have been obvious to have used n-heptanoic acid for the treatment of cardiac disorders such as cadiac myopathy and or cardiac muscle weakness because Heart failure is associated with alterations in cardiac and skeletal muscle energy metabolism resulting in a generalized myopathy. As evidence by Iwama et al, myocardial infarction results from cardiomyopathy. See entire reference. As to instant claim 25, it is expected that the claimed compound would reduce efficiency of a metabolic pathway of heart tissue.

Even though, the reference did not identify heptanoic acid as n-heptanoic acid one of ordinary skill in the art would know and recognize that the heptanoic acid used is unbranched, and n-heptanoic acid is an unbranched heptanoic acid. Therefore, it would have been obvious to have used the n-heptanoic acid (unbrabranched form) for the treatment of cardiac myopathy, because heptanoic acid have been known to be used in cardiac disorders and cardiac myopathy or cardiac muscle weakness is a cardiac disorder.

Double Patenting

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn.

Claims 17,19-47 and 49-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 25-27, 37-40, 42-45 and 47-56 of U.S. Patent No. 10/371,385. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

The copending application teaches an infant formula for increasing growth rate comprising seven carbon fatty acids such as n-heptanoic acid and a triglyceride comprising n-heptanoic acid (n-heptanoin). The present application teaches methods of treating a patient with a cardiac disorder comprising administering the instant composition of the copending application. The method claims of the present application are an obvious variation of the claims of the copending application.

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 17, 19-47 and 49-57 and copending application claims 25-27, 38-40, 42-45 and 47-56. As evident by Salzer et al., infants with congenital heart disease have poor weight and length gain (see introduction) and, therefore, need a nutritional supplement. The claimed compositions would have been obvious to one of ordinary skill in the art to use in the treatment of infants with congenital heart disease suffering from poor weight gain.

In view of the foregoing, the copending application claims and the current application claims are obvious variants.

Claims 17,19-47 and 49-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-18 and 21-36 of copending Application No. 10/748432, in view of Rice et al., Neurology

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application teaches an infant formula comprising seven carbon fatty acids such as n-heptanoic acid and a triglyceride

comprising n-heptanoic acid (n-heptanoin) in the treatment of a metabolic disorder. The present application teaches methods of use claims containing the instant composition in treating a cardiac disorder. As evident by Rice et al., a metabolic disorder comprises cardiac disorders (see pg. 4 underlined). Thus one of ordinary skill in the art would have been motivated to administer the same composition with a seven carbon chain acid (n-heptanoic acid) to a patient suffering from either a metabolic or cardiac disorder (fatty acid oxidation defects). See pg. 4 as above. Therefore, the copending claims therein are obvious variants of the claims of the instant application.

These are a provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
1/8/08

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER